

Fees for e-cigarette notifications

Department of Health/Medicines and Healthcare products Regulatory Agency

RPC rating: fit for purpose

The IA is now fit for purpose as a result of the department's response to the RPC's initial review. As first submitted, the IA was not fit for purpose.

Description of proposal

As a requirement of the EU Tobacco Products Directive, the Medicines and Healthcare products Regulatory Agency (MHRA) must provide a notification service for e-cigarette products for the UK market. Under the Directive, e-cigarette producers will need to provide the MHRA with ingredients and emissions data for each separate product. In line with Government policy to set charges to recover full costs, the proposal allows the MHRA to recover the costs of the notification system.

Impacts of proposal

The cost of the notification system is estimated to be £2 million in year one and around £0.8 million in each subsequent year. The MHRA operates on a full cost recovery basis, so the full cost will be passed on to e-cigarette producers, and importers in the form of fees. The MHRA estimates that there will be approximately 14,000 notifications in the first year and 2,000 in subsequent years. For each notification, businesses will need to pay a notification fee. The Department also estimates that from year two, there will be around 2,000 modifications to products each year. This will require businesses to pay a modification fee. Each notified product will also need to pay an annual periodic fee.

The MHRA recognises that costs for year two onwards are illustrative at this stage and will be reviewed at the end of year one to avoid MHRA running a surplus or deficit. The IA further explains that any familiarisation costs of the notification system have been accounted for within the Tobacco Products Directive IA.

The RPC verifies the estimated equivalent annual net cost to business (EANCB) of £1.0 million. In line with the Small Business, Enterprise and Employment Act, as the proposal covers a fee or charge, this will not be considered a regulatory provision.

Quality of submission

As initially submitted, the IA included issues that meant that the RPC did not consider it fit for purpose as the IA did not provide sufficient evidence to support the estimated costs of the proposal. Following the RPC's initial review, the Department submitted a revised IA that responds to the points made in the initial review.

The Department has now provided further evidence to support the estimated costs resulting from the proposal. However, the IA would have benefitted from providing greater explanation of the precise nature of each of the three proposed fees, in particular the periodic fee. The Department has also provided further explanation of how this proposal interacts with the Tobacco Products Directive (TPD). The TPD IA sets out the regulatory costs of the notification scheme. This IA revises the cost estimates to reflect the level of fees proposed by the MHRA.

Other comments

A SaMBA is required as this is a domestic measure requiring Reducing Regulation Committee clearance. The TPD does not exempt such businesses from the notification requirements but these businesses could be exempted from paying the fees. Therefore, the exemption of such businesses from these proposals could still allow the Department to achieve the policy objective of providing a notification scheme as required by the TPD. The IA would have benefitted from greater consideration of exempting small businesses from the charges. However, the Department has explained that industry estimates that around 90% of businesses in the e-cigarette sector are designated as small and micro businesses and the Department intends to mitigate any potential familiarisation costs through a communication campaign and by keeping the costs and fees as low as possible.

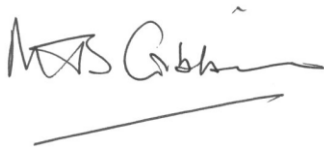
Departmental assessment

Classification	Not a regulatory provision (fees and charges)
Equivalent annual net cost to business (EANCB)	£1.0 million
Business net present value	-£4.7 million
Societal net present value	£0 million

RPC assessment

Classification	Not a regulatory provision (fees and
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	charges)
EANCB – RPC validated ¹	£1.0 million
Business Impact Target (BIT) Score ¹	£0 million
Small and micro business assessment	Sufficient
RPC rating (of initial submission)	Not fit for purpose



Michael Gibbons CBE, Chairman

¹ For reporting purposes, the RPC validates EANCB and BIT score figures to the nearest £100,000.